OCT 5 - 2005

510(k) Summary of Safety and Effectiveness for the MED flash II Intense Pulsed Light System K051508

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	General Project S.r.l. Via della Gora 15/19 50025 Montespertoli Firenze, Italy
Contact Person:	Maureen O'Connell 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	June 1, 2005

2. **Names**

Device Name:	MED flash II Intense Pulsed Light System
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. **Predicate Devices**

The MED flash II Intense Pulsed Light System is substantially equivalent to a combination of the following devices: Palomar's StarLux V (K041086, K033549), Palomar's EsteLux V (K040081), Palomar's EsteLux G (K020941), Lumenis' IPL Quantum SR and the Real Time Chiller (K020839), Novalis Medical's Clareon Pulsed Light System (K043319), Cutera's Optional Pulsed Light Hand Piece Family (K050047), Cynosure's Photosilk and Photosilk Plus (K041095) and General Project's Flash 1 (K022583).

4. **Device Description**

The MED flash II Intense Pulsed Light System is a medical device emitting light radiation in the range from 590 nm to 1200 nm. The system is based on a quick power discharge of capacitors in a Xenon lamp, mounted on a handpiece. This generates a rapid and Intense Pulsed Light.

The Med flash II system contains five principal components:

- Charge system of the capacitors
- Electronic control system
- Control panel
- Handpiece with exchangeable lamp box
- Handpiece cooling system

5. **Indications for Use**

The MED flash II Intense Pulsed Light System which is generally indicated for use in:

- Removal of unwanted hair from all skin types and to effect stable long-term or permanent, hair reduction
- Treatment of inflammatory acne (acne vulgaris)
- Treatment of benign pigmented epidermal and cutaneous lesions including warts, scars, striae, lentigines, nevi, melasma and café-au-lait
- Treatment of vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins
- The integrated cooling handpiece is intended to provide pre-cooling of the epidermis, to reduce thermal injury to the epidermis, and to reduce patient pain, & discomfort associated with light applications.

6. **Performance Data**

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2005

General Project S.r.l.
c/o Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K051508
Trade/Device Name: MED flash II Intense Pulsed Light System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 25, 2005
Received: August 26, 2005

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

Device Name MED flash II Intense Pulsed Light System

Indications for Use:

The MED flash II Intense Pulsed Light System is indicated for use in:

- Removal of unwanted hair from all skin types and to effect stable long-term or permanent, hair reduction
- Treatment of inflammatory acne (acne vulgaris)
- Treatment of benign pigmented epidermal and cutaneous lesions including warts, scars, striae, lentigines, nevi, melasma and café-au-lait
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- The integrated cooling handpiece is intended to provide pre-cooling of the epidermis, to reduce thermal injury to the epidermis, and to reduce patient pain, & discomfort associated with light applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051508